510(k) Summary

Submission Date:	25 January 2013
Submitter:	Spacelabs Healthcare 1 Harforde Court John Tate Road Hertford SG13 7NW United Kingdom
Submitter Contact:	Mr. Al Van Houdt Spacelabs Healthcare Phone: +1 (425) 657-7200, ext 5970 Fax: +1 (425) 657-7210 Email: al.vanhoudt@spacelabs.com
Application Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Manufacturing Site:	Edan Instruments, Inc. 2/F And 5/F, Block A/B, Unit 8, Xing Hua Building, Nanhai Rd, Nanshan Shenzhen CHINA 518067
Trade Name:	Spacelabs Healthcare CardioExpress, Models 98400-SL3-IEC, 98400-SL3-AHA, 98400-SL6-IEC, 98400-SL6-AHA, 98400-SL12-IEC, and 98400-SL12-AHA
Common Name:	Electrocardiograph
Classification Name:	Electrocardiograph
Classification Regulation:	21 CFR §870.2340
Product Code:	DPS

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Substantially Equivalent Devices:	*New Spacelabs Models*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Spacelabs Healthcare CardioExpress, Models 98400-SL3-IEC, 98400-SL3-AHA, 98400-SL6-IEC, 98400-SL6-AHA, 98400-SL12-IEC, and 98400-SL12-AHA	K090367	Edan Instruments, Inc. / SE-601 Series Electrocardiograph
		K091513	Edan Instruments, Inc. / SE-3, SE-300A, SE-300B, SE-6, SE-600, SE-12, SE-12 Express, SE-1200 AND SE-1200 Express

Device Description:

The Spacelabs Healthcare (Spacelabs) CardioExpress, Models 98400-SL3-IEC, 98400-SL3-AHA, 98400-SL6-IEC, 98400-SL6-AHA, 98400-SL12-IEC, and 98400-SL12-AHA, are a series of electrocardiographs (ECGs) designed to acquire, analyze, display, and record ECG signals from ECG electrodes connected to a patient.

After been amplified, filtered and analyzed, the ECG signal waveforms and analysis results are presented on a liquid crystal diode (LCD) display, and recorded on the paper through either a thermal or USB printer. ECG data, result and patient information may be stored in the memory file. The file can be transmitted to a personal computer (PC) through either an UART or Ethernet connection.

The CardioExpress can optionally contain auto analysis software which assists in performing auto measurement and auto interpretation of data. The CardioExpress consists of two (2) basic components: (1) the signal acquisition module, and (2) the central processing unit. All models contain a rechargeable battery.

The CardioExpress series of ECG monitors are provided in three (3) primary models: CardioExpress SL-3; CardioExpress SL-6; and CardioExpress SL-12.

Intended Use:

The intended use of the Spacelabs Healthcare CardioExpress (CardioExpress) is to acquire ECG signals from adult and pediatric patients using ECG electrodes. CardioExpress is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by CardioExpress can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements are only intended to be used on adult patients, and is offered to clinicians on an advisory basis only.

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Technology Comparison: CardioExpress employs the same technological characteristics as the predicate devices.

	Characteristic	*Predicate Devices*	*Proposed Devices*
CardioExpress SL-3	*Channels*	3	Same
	Lead Color Coded Option	AHA and IEC	Same
	Leads	12 standard	Same
	Acquisition Mode	12 simultaneous leads	Same
	Heart Rate Recognition Technique	Peak-to-peak detection	Same
	Heart Rate Range	30 – 300 beats per minute (BPM)	Same
	Recorder	Thermal dot-matrix recorder	Same
CardioExpress SL-6	*Channels*	6	Same
	Lead Color Coded Option	AHA and IEC	Same
	Leads	12 standard	Same
	Acquisition Mode	12 simultaneous leads	Same
	Heart Rate Recognition Technique	Peak-to-peak detection	Same
	Heart Rate Range	30 – 300 beats per minute (BPM)	Same
	Recorder	Thermal dot-matrix recorder	Same
CardioExpress SL-12	*Channels*	12	Same
	Lead Color Coded Option	AHA and IEC	Same
	Leads	12 standard	Same
	Acquisition Mode	12 simultaneous leads	Same
	Heart Rate Recognition Technique	Peak-to-peak detection	Same
	Heart Rate Range	30 – 300 beats per minute (BPM)	Same
	Recorder	Thermal dot-matrix recorder	Same

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Summary of Performance Testing:

Software Testing

Software was designed and developed according to a robust software development process, and was rigorously verified and validated. Software information is provided in accordance with internal requirements and the following standards and guidance documents:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02; and*
- *FDA guidance: Cybersecurity for networked medical devices containing off-the-shelf (OTS) software, 14 January 2005.*

Test results indicate that the CardioExpress complies with its predetermined specifications and the applicable standards and guidance documents.

Electrical Safety Testing

CardioExpress was tested for performance in accordance with the following Standard:

- *IEC 60601-1: 1988, Am1: 1991, and Am2: 1995, Medical electrical equipment, Part 1: Particular requirements for safety.*

Test results indicated that CardioExpress complies with the Standard.

Electromagnetic Compatibility Testing

CardioExpress was tested for performance in accordance with the following Standard:

- *IEC 60601-1-2: 2001, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.*

Test results indicated that CardioExpress complies with the Standards.

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Performance Testing

CardioExpress was tested for performance in accordance with internal requirements and the following standards:

- *IEC 60601-1-6: 2004, Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability;*
- *IEC 60601-1-8: 2003, Am1: 2006, Medical electrical equipment – Part 1-8: General requirements for safety – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems;*
- *IEC 60601-2-25: 1993, Am: 1999, Medical electrical equipment – Part 2-25: Particular requirements for the safety of electrocardiographs; and*
- *IEC 60601-2-51: 2003, Medical electrical equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs.*

Test results indicate that CardioExpress complies with its predetermined specifications and the applicable standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of CardioExpress. The results of these activities demonstrate that CardioExpress is safe and effective when used in accordance with its intended use and labeling.

Therefore, CardioExpress is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2013

Spacelabs Healthcare Ltd.
c/o Mr. Thomas Kroenke
PO Box 3018
Nederland, CO 80466

Re: K130207
Trade/Device Name: CardioExpress Electrocardiographs (SL3, SL6, and SL12)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 24, 2013
Received: June 24, 2013

Dear Mr. Thomas Kroenke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):	K130207
Device Name:	Spacelabs Healthcare CardioExpress, Models 98400-SL3-IEC, 98400-SL3-AHA, 98400-SL6-IEC, 98400-SL6-AHA, 98400-SL12-IEC, and 98400-SL12-AHA
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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2013.07.23
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